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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,190	01/24/1997	HANS-PETER JOSEL	P564-7002	1643

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/776,190	JOSEL ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-77,81-89,100 and 107-115 is/are pending in the application.
- 4a) Of the above claim(s) 82 and 89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-77,81,83-88,100 and 107-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 72-77, 81-89, 100 and 107-115 are pending. Claims 82 and 89 remain withdrawn from consideration as drawn to non-elected species, there currently being no allowable generic claim. Claims 72-77, 81, 83-88, 100 and 107-115 are examined herein to the extent of the elected species.

Status of the Rejections

2. The written description rejection under 35 U.S.C. 112, first paragraph is maintained. One of the rejections under 35 U.S.C. 112, second paragraph, is withdrawn; the remaining rejections under 35 U.S.C. 112, second paragraph, are maintained. The prior art rejections over Tam (US 5,229,490) and Rose et al. (US 6,001,364) are maintained.

Claim Rejections - 35 USC § 112, First Paragraph

Maintained Claim Rejections

3. Claims 72-77, 81, 83-88, 100 and 107-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. This rejection maintains the reason of record as set forth in the previous Office action, mailed 2/25/2004.

In the Reply, filed 6/28/2004, to the previous Office action, applicant argues as of the filing date sought, the specification clearly conveys that applicants were in "complete possession" of conjugates in which individual groups are incorporated in the carrier at defined and reproducible "predetermined positions". Also, applicant argues as of the filing date sought, applicants were in complete possession of conjugates containing "non-immunologically reactive" carriers.

Response to Arguments

Applicant's arguments filed 6/28/2004, have been fully considered but they are not persuasive.

Applicant assertion that the specification conveyed to the practitioner that applicant was in possession of the claimed invention does not, alone, satisfy the written description requirement of 35 U.S.C. 112, first paragraph. In University of Rochester v. G.C. Searle & Co., Inc., No. 03-1304 (Fed. Cir. Feb. 13, 2004) the Federal Circuit, quoted Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 969 (Fed. Cir. 2002):

Application of the written description requirement, however, is not subsumed by the 'possession' inquiry. A showing of 'possession' is ancillary to the statutory mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the invention.

Enzo, 323 F.3d at 969. Thus the specification must teach the invention by describing it.

The terminology "predetermined positions", found in the claims, does not convey structural limitations that would permit a person of skill in the art to determine what the invention is. For example, a practitioner would not be able to distinguish between the claimed invention, and fragments, 100 amino acids or less in length, of natural proteins

that had been conjugated to haptens, markers or solid phase binding groups. Absent evidence to the contrary, conjugation to a natural protein fragments would not be at predetermined positions. The claims provide no notice to the practitioner of structural differences that would result from placement of conjugates at so-called predetermined positions. In University of Rochester v. G.C. Searle & Co., Inc., No. 03-1304 (Fed. Cir. Feb. 13, 2004) the Federal Circuit, quoted from *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822) in stating that the specification must “put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.”

Similarly, the usage of the term “non-immunologically reactive” found in claim 110 does not describe structural limitations that would result from “non-immunologically reactive” carriers. It has long been appreciated in the art from the classic experiments of Landsteiner, that molecules which are not immunogenic, can be made to be immunogenic, by conjugating them (as haptens) to carrier proteins. Thus one of skill in the art would not know what carriers would be encompassed by the term “non-immunologically reactive”, because assay conditions would decide whether or not a carrier is non-immunologically reactive. In University of Rochester v. G.C. Searle & Co., Inc., No. 03-1304 (Fed. Cir. Feb. 13, 2004) the Federal Circuit, quoted *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002):

[T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening

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inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [Regents of the Univ. of Cal. v.] Eli Lilly [& Co., Inc.], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) ("Lilly")] The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Id.*

Enzo, 323 F.3d at 968.

Therefore, the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Withdrawn Claim Rejections

4. The rejection of claims 72-77, 81, 83-88, 100 and 107-115, under 35 U.S.C. 112, First Paragraph, (New Matter), is withdrawn. This rejection is withdrawn in view of applicant's arguments and amendments to claims 72 and 100, filed 6/28/2004.

Claim Rejections - 35 USC § 112, Second Paragraph

Maintained Claim Rejections

5. Claims 72-77, 81, 83-88, 100 and 107-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record, as set forth in the previous Office action, mailed 2/25/2004.

6. Claims 72 and 100, and their dependent claims, recite the language “predetermined positions on the polymeric carrier, such that distances between the hapten molecules and the marker groups or solid phase binding groups are defined thereby”, which renders the claims vague and indefinite.

In the Reply, filed 6/28/2004, to the previous Office action, applicant argues that the specification as filed sets forth the meaning of the term “predetermined positions on the polymeric carrier, such that distances between the hapten molecules and the marker groups or solid phase binding groups are defined thereby” to one of skill in the art; and that applicant are their own lexicographers.

Response to Arguments

Applicant's arguments filed 6/28/2004, have been fully considered but they are not persuasive. Applicant's recited language of “predetermined positions on the polymeric carrier, such that distances between the hapten molecules and the marker groups or solid phase binding groups are defined thereby” appears to read upon a mental step. It remains unclear as to whom the claimed positions are predetermined. Also, it is unclear as to whether the language refers to a mental step or attempts to refer to a structural limitation of the claimed product. It is not disputed that applicant may be their own lexicographer. The examiner does not argue that the term is repugnant to the usual usage in the art. Rather, it is that the claims or the specification do not reasonably apprise of one skill in the art as to the metes and bounds of the claimed invention.

7. Claim 110 recites the language “non-immunologically reactive”, which renders the claims vague and indefinite.

In the Reply, filed 6/28/2004, to the previous Office action, applicant argues that the specification as filed sets forth the meaning of the term “non-immunologically reactive” to one of skill in the art; and that applicant are their own lexicographers.

Response to Arguments

Applicant's arguments filed 6/28/2004, have been fully considered but they are not persuasive. It remains unclear as to what identifies a carrier that is “non-immunologically reactive”. As stated in the previous Office action, this term is relative, because it is not clear what structural features produce a carrier that is “non-immunologically reactive”, regardless of the assay conditions. It is not disputed that applicant may be their own lexicographer. The examiner does not argue that the term is repugnant to the usual usage in the art. Rather, it is that the claims or the specification do not reasonably apprise of one skill in the art as to the metes and bounds of the claimed invention.

Withdrawn Claim Rejections

8. The rejection of claim 87, under 35 U.S.C. 112, second paragraph, is withdrawn. Claim 87 was rejected for being vague and indefinite because it recites the term “pharmacologically active”. This rejection is withdrawn in view of applicant's arguments and Exhibit 1, filed 6/28/2004.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Claim Rejections

9. Claims 72, 74, 75, 86-88, 100, 107, 110, and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Tam (US 5,229,490). This rejection is maintained for the reasons of record, as set forth in the previous Office action, mailed 2/25/2004.

In the Reply, filed 6/28/2004, to the previous Office action, applicant argues that the reference of Tam does not teach all limitations of the claims. In particular, applicant points to Tam et al. at col. 10, lines 27-34, in regarding diagnostic moieties as marker groups, and argues that Tam does not teach or suggest a carrier that "simultaneously contains both a hapten (e.g., a peptide antigen) and a marker groups." Applicant argues that the solid phase binding groups, as taught by Tam et al., are not coupled to amino groups or thiol groups, as required by the claimed invention. Applicant argues that the dependent claims contain additional limitations that render said claims distinguishable from Tam.

Response to Arguments

Applicant's arguments filed 6/28/2004, have been fully considered but they are not persuasive.

The examiner respectfully submits that the reference of Tam et al. *does* teach a carrier that simultaneously contains both a hapten molecule and a marker group. In the

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paragraph immediately following the paragraph cited by applicant, and in reference to use as a diagnostic agent, the reference of Tam states:

The products of the invention may be employed in various diagnostic tests including radioimmunoassay, precipitation, complement fixation, direct and indirect immunofluorescence, agglutination and enzyme linked immunoassay. For such testing the diagnostic moiety joined to the dendritic polymer may be *labeled with a detectable label*, or it may be caused to react with a labeled product such as a labeled antibody to product a detectable reaction product.

Tam et al., at col. 10, lines 40-48 (emphasis added).

Thus Tam et al., teach a diagnostic moiety attached to a polymer wherein the diagnostic moiety contains both a hapten and a detectable label, *i.e.*, a marker. Absent evidence to the contrary, the term “diagnostic moiety” as found in Tam et al., is taken to encompass the “hapten molecules” of the claimed invention. This is reasonable; because Tam et al. contemplates the use of various immunoassays (e.g., “radioimmunoassay, precipitation, complement fixation, direct and indirect immunofluorescence, agglutination and enzyme linked immunoassay”), which use antigens (such as haptens) in their diagnostic procedures. Applicant’s view of Tam’s diagnostic moiety as a marker group, is not consistent with Tam’s teaching that a diagnostic moiety may be labeled with a marker group (*i.e.*, “detectable label”).

Applicant argument that the solid phase binding groups, as taught by Tam et al., are not coupled to amino groups or thiol groups, is persuasive; but is moot, particularly in view of the further teachings of Tam et al., (see above). Applicant argues that the dependent claims contain additional limitations that render said claims distinguishable

from Tam, but because those additional limitations are not identified, said argument is not addressed further.

10. Claims 72, 74-76, 86-88, 100, 107, 110, and 111 are rejected under 35 U.S.C. 102(e) as being anticipated by Rose et al. (US 6,001,364). This rejection is maintained for the reasons of record, as set forth in the previous Office action, mailed 2/25/2004.

In the Reply, filed 6/28/2004, to the previous Office action, applicant argues that the reference of Rose et al. does not teach all elements of the rejected claims. Applicant argues that the hapten molecules of Rose et al. are not coupled to reactive side groups that are amino groups or thiol groups, but instead are coupled to side groups that are oxime groups. Applicant points to col. 8, lines 20-26, and col. 11, lines 8-35, to show that the ϵ -amino side groups of the "baseplate" amino acid polymer of Rose et al. are first converted to oxime groups, to which complementary orthogonal specifically active molecules (COSM) are bound.

Response to Arguments

Applicant's arguments filed 6/28/2004, have been fully considered but they are not persuasive.

Applicants claim a product, but argue that the process by which that product is made, distinguishes the prior art reference of Rose et al. In particular, Rose et al. teach reaction with the ϵ -amino side group of lysine ($-\text{NH}_3^+$), as encompassed by the claimed invention. Rose et al. teach reacting said amino group to convert it to an oxime ($=\text{N}-$

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OH), which is then reacted with the COSM (hapten, etc). The examiner respectfully notes that the instant Specification, at p. 9, para 3, states that a spacer may be incorporated "between the hapten and the marker or solid phase binding group and the carrier chain."

It is the examiner's position that as the art teaches that it is an amino side group that has been reacted in order to attach the hapten or marker or solid phase binding group, and as it is not necessary to the claimed invention that the hapten be directly attached to the amino group, (the attachment may occur through spacers), the products formed by the process of Rose et al. are indistinguishable from the products of the claimed invention. The examiner respectfully submits that, absent evidence to the contrary, the claimed product does not comprise a structural limitation that results from the hapten or marker or binding group, directly reacting with an amino side group. Also, the product of the claimed invention does not comprise a structural feature which is prevented by the amino side group engaging in an initial first reaction, (e.g., changing the amine to an oxime), that does not immediately couple a hapten or a marker or a solid phase binding group to the polymer carrier.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Claim Rejections

11. Claims 72, 74-75, 81, 86-88, 100, and 107-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Tam (US 5,229,490). This rejection is maintained for the reasons of record, as set forth in the previous Office action, mailed 2/25/2004.

In the Reply, filed 6/28/2004, to the previous Office action, applicant argues that Tam et al. does not teach or suggest all elements of the claimed invention.

Response to Arguments

Applicant's arguments filed 6/28/2004, have been fully considered but they are not persuasive. As stated in the Response to Arguments for the rejection under 35 U.S.C. 102(b) over Tam et al., the reference of Tam teaches and suggests hapten molecules and marker groups or solid phase binding groups that are coupled to a polymeric carrier by reactive amino groups.

12. Claims 72-76, 81, 86-88, 100, and 107-111 are rejected under 35 U.S.C. 102(e) as being anticipated by Rose et al. (US 6,001,364). This rejection is maintained for the reasons of record, as set forth in the previous Office action, mailed 2/25/2004.

In the Reply, filed 6/28/2004, to the previous Office action, applicant argues that Rose et al. does not teach or suggest all elements of the claimed invention.

Response to Arguments

Applicant's arguments filed 6/28/2004, have been fully considered but they are not persuasive. As stated in the Response to Arguments for the rejection under 35 U.S.C. 102(b) over Rose et al., the reference of Rose teaches and suggests haptens

molecules and marker groups or solid phase binding groups that are coupled to a polymeric carrier by reactive amino groups.

Conclusion

13. Claims 72-77, 81, 83-88, 100 and 107-115 are rejected. Claims 82 and 89 remain withdrawn from consideration.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

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PADMASHRI PONNALURI
PRIMARY EXAMINER